K072977

JUL 16 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's name:	Diazyme Laboratories
Submitter's address:	12889 Gregg Court Poway, CA 92064 USA
Name of Contact Person:	Dr. Abhijit Datta Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 Phone: 858-455-4762 Fax: 858-455-2120
Date the Summary was Prepared:	September 24, 2007, June 5, 2008, and July 8, 2008
Name of the Device	Diazyme Apolipoprotein A-I Assay
Trade Name:	Diazyme Apolipoprotein A-I Assay
Common/Usual Name	Apolipoprotein A-I Test System
Device Classification Name	Lipoprotein test system
Product code:	MSJ (reagent), JIT (calibrator), JJX (control)
Submission Type	510k
Regulation Number	862.1475(reagent), 862.1150(calibrator), 862.1660(control)
Device Class	II (reagent), II (calibrator), I Reserved (control)
Predicate Device:	For the Alpha-1-lipoprotein Immunological Test System Lipoprotein test system, we are claiming equivalence [807.92(a) (3) to K-ASSAY APO AI ASSAY (k993345) manufactured by Kamiya Biomedical Company

Substantial Equivalence Information

1. **Predicate device name(s):**

   K-Assay Apo AI Assay

2. **Predicate 510(k) number(s):**

   K993345

3. **Comparison with predicate:**

Indications for Use

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
The Diazyme Apolipoprotein A-I Assay is intended for the *in vitro* quantitative determination of apolipoprotein A-I (apo A-I) in serum. It can be used as an aid for assessing the risk of coronary artery disease.	For the quantitative determination of human Apolipoprotein AI (Apo AI) in serum by immunoturbidimetric assay.	Same

Principle

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
This method is based on the reaction of a sample containing human Apo A-I and specific antiserum to form an insoluble complex which can be measured turbidimetrically at 340nm. By constructing a standard curve from the absorbance of standards the concentration of Apo A-I can be determined.	This method quantifies Apolipoprotein AI based on immunoturbidimetric assay. The reagent uses a goat polyclonal antibody specific for human Apolipoprotein AI. The antibody binds to the Apo AI in the serum forming light scattering immune complexes, which increase the turbidity of the sample. Since the turbidity is proportional to the amount of Apo AI in the sample, the Apolipoprotein AI concentration can be determined by measuring this increase in turbidity. The increase in turbidity is measured at 800 nm. Apolipoprotein AI in the sample is quantitatively determined.	Similar

Test Objective

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
The Diazyme LDL-Cholesterol Assay is intended for the in vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma.	For the quantitative determination of human Apolipoprotein AI (Apo AI) in serum by immunoturbidimetric assay.	Same

Type of Test

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
Quantitative	Quantitative	Same

Specimen Type

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
Human serum	Human serum	Same

Product Type

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
Calibrator, Reagent, Instrument	Calibrator, Reagent, Instrument	Same

Performance

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay
Reportable Range: Serum: **20- 228 mg/dL** Precision/Serum: Within Run: **0.6% -0.9%** Total: **1.8%–3.3%** Accuracy/Serum: Correlation Coefficient: **0.9789** Slope/Intercept: **y = 0.91+ 2.813**	Reportable Range: Serum: **20 – 300 mg/dL** Precision/Serum: Within Run: **1.51% -1.87%** Total: **1.05%–1.57%** Accuracy/Serum: Correlation Coefficient: **0.970** Slope/Intercept: **y = 0.980x + 4.776 mg/dL**

Calibrator Comparison

Diazyme Apolipoprotein A-I Assay	K-Assay Apo AI Assay	Equivalency
Lyophilized form	Lyophilized form	Same
Diazyme Apolipoprotein A-I calibrator value is traceable to the WHO International Reference Material for Apo AI, Sp1-01.	K-Assay Apo AI calibrator value is traceable to the WHO International Reference Material for Apo AI, Sp1-01.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 16 2008

General Atomics
Diazyme Laboratories
c/o Mr. Charles Yu, Quality System Manager
12889 Gregg Court
Poway, California 92064

Re: k072977
Trade Name: Diazyme Apolipoprotein A-I Assay;
Diazyme Apolipoprotein A-I Calibrator, and
Diazyme Apolipoprotein A-I Control,
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, meets the limitation to exemption in 862.9(c)(4)
Product Code: MSJ, JIT, JJX
Dated: June 5, 2008
Received: June 17, 2008

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K072977

Device Name: Diazyme Apolipoprotein A-I Assay

Indications for Use: The Diazyme Apolipoprotein A-I Assay is intended for the *in vitro* quantitative determination of apolipoprotein A-I (apo A-I) in serum. It can be used as an aid for assessing the risk of coronary artery disease. For *in vitro* Diagnostic use.

Calibrator: For calibration of the Diazyme Apolipoprotein A-I Assay in serum. For *in vitro* Diagnostic Use.

Controls: To monitor the performance of Diazyme Apolipoprotein A-I Assay in serum. For *in vitro* Diagnostic Use.

Division Sign-Off

Office of In Vitro Diagnostic Device **Evaluation** and Safety

510(k) K072977

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)